Review Article

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Stem cell research: The India perspective

Stem cell therapy is being billed as the next panacea for all ills. The immense potential that has been shown by stem cells in treatment of diseases traditionally considered "degenerative, incurable and irreversible" such as diabetes, heart disease, spinal cord injuries, Parkinson's, Alzheimer's disease has brought them into the spotlight. Research in human developmental biology has led to the discovery of human stem cells (precursor cells that can give rise to multiple tissue types), including embryonic stem (ES) cells, embryonic germ (EG) cells, and adult stem cells. Techniques have been developed for the *in vitro* culture of stem cells, providing opportunities for studying and understanding human embryology. As a result, scientists can now carry out experiments aimed at determining the mechanisms underlying the conversion of a single, undifferentiated cell, the fertilized egg, into the different cells comprising the organs and tissues of the human body. Although it is impossible to predict the outcomes, scientists and the public will gain immense new knowledge in the biology of human development that will likely hold remarkable potential for therapies and cures. Derivation of ES cells from early human embryos, and EG and fetal stem cells from aborted, fetal tissues raise ethical, legal, religious, and policy questions. Further, the potential use of stem cells for generating human tissues and, perhaps, organs, is a subject of ongoing public debate.[1]

The debate around stem cells as therapy includes several sociopolitical, cultural and ethical issues.

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In addition to the ethical issues that surround all clinical research there are additional facets added to stem cell research due to the use of human embryos, manipulations and modifications. In this article we will try to assess the perspective of stem cell research in India.

Stem cell research conducted by developing countries offers the potential to target innovation to local context, make treatments more affordable, and aid in economic development.[2]

Propelled by the scientific and economic promise of important new health technologies, stem cell science has produced politicization across the international, regional and national policy domains.

Concerned lest they should lose an important opportunity, the emerging economies like India are introducing policies designed to improve their global competitive position in this field. Given that their science, tax regimes, regulation, supporting industries and financial markets are at a different stage of evolution to that of the developed economies, India faces unique challenges in the fluid arena of stem cell globalization.[3]

REGULATION OF RESEARCH IN INDIA

The clinical research environment in India is currently undergoing a tremendous flux, with regulators coming under severe criticism from the press, public and the elected government.[4]

There are the new ICMR-DBT draft guidelines on stem cell research, and the CDSCO draft on compensation towards injury due to participation in clinical research that are responses to several questions that face us today.[5,6]

If these guidelines are to have lasting credibility then

they must not only be implemented but, so far as the international scientific community is concerned, be seen to be implemented.

ETHICAL ISSUES IN EMBRYONIC STEM CELL RESEARCH

In India, the relationship between the supply of embryos for hESC research and the political and cultural context is a complex one. India's IVF clinics are an established source of embryos for research to which foreign scientists come for supplies (Jayaraman 2001). However, in the wake of the setting up of the ESC line research at Reliance Life Sciences Laboratory and the National Centre of Biological Sciences in 2001 and its associated publicity, the government announced a "crack down" on the trade to counter the international view of India as "an embryo surplus" nation (Express Healthcare Management 2001). Given the medical profession's entrenched resistance to the regulation of IVF, an area of their work that in India is both sparsely monitored and highly lucrative, the government's proposals are unlikely to be implemented diligently. If they are not, there is no reason to suppose that there will be much public conflict on this issue. The cultural intricacies, stigmas and taboos surrounding infertility in Indian culture seem more likely to promote a self-protective silence on the moral status of the human embryo rather than an open discussion (Bharadwaj 2005).

Moreover, as stem cell therapies move into the later stages of development, the field will be confronted with many of the problems that currently plague the conduct of pharmaceutical trials in general. As India becomes a global center for clinical trials, the question of ethical oversight becomes increasingly difficult to ignore. It is significant that the current guidelines for human subject experimentation were established after an incident in 1999, prompting the government to order a review of safety and ethical standards.

The Ethical guidelines for biomedical research on human subjects were published by the Indian Council for Medical Research (ICMR) in 2000. However, their recommendations are non-binding and scandals continue to emerge (Padma 2005b). At the same time, the Drugs Controller General has issued binding regulations on Good clinical practices for clinical research in India (2001), based on World Health Organization standards, and it is reported that programs to train clinicians in GCP are proliferating around the country (Kahn 2006).

The Guidelines propose a system of review and monitoring of the field based on a National Apex Committee (NAC) for Stem Cell Research and Therapy and, at the institutional level, Institutional Committees for Stem Cell Research and Therapy. All research, including clinical trials, would require the prior approval of, and be registered with, the NAC. Prohibited areas of research include reproductive cloning, implantation of a human embryo into the uterus after *in vitro* manipulation, and transfer of human blastocysts generated by somatic cell nuclear transfer (SCNT) into a human or nonhuman uterus. Studies of chimeras and the creation of a zygote by IVF or SCNT with the specific aim of deriving a hES line are restricted but not prohibited.

But without legal backing for the Guidelines, Indian stem cell scientists feel free to consult their own consciences and make their own decisions. In principle, they should abide by the principles of the ICMR's Ethical guidelines for biomedical research on human subjects published in 2000. However, a 2005 survey by ICMR showed that in the absence of any powers of enforcement only a minority choose to do so: 40 (22%) of India's 179 institutional ethics committees followed the principles laid down in this document (Mudur 2005).[7]

As stem cell science moves from the laboratory to the clinic and the experimental treatment of patients, in India it does so in a governance vacuum (Padma 2006). As a result, scientists like Dr. Geeta Shroff can publicize her treatment of 100 clinical cases of spinal injuries, paralysis, tuberculosis, neuro-muscular dystrophy and multiples sclerosis conducted without ICMR approval and receive simultaneous praise from the Indian Health Secretary and condemnation from Western stem cell scientists (Ramesh 2005).

CONCLUSION

The growing global interest in stem cell research & therapy mandates development of a robust regulation and oversight along with steps to enhance public knowledge and awareness. Embryonic stem cells should be obtained from embryos remaining from infertility procedures after the embryo's progenitors have made a decision that they do not wish to preserve them. This decision should be explicitly renewed prior to securing the progenitors' consent to use the embryos in ES cell research.

Persons considering donating their excess embryos for research purposes should be afforded the highest standards of protection for the informed consent and voluntariness of their decision.

Special efforts should be made to promote equitable access to the benefits of stem cell research.

Intellectual property regimes for stem cell research should set conditions that do not restrict basic research or encumber future product development. It is essential that there be a public that is educated and informed about the ethical and policy issues raised by stem cell research and its applications. Informed public discussion of these issues should be based on an understanding of the science associated with stem cell research, and it should involve a broad cross-section of society. It is essential for citizens to participate in a full and informed manner in public policy deliberations about the development and application of new technologies that are likely to have significant social impact.

The understanding of the science is particularly important for discussing ethical and policy issues. Ideally, scientists should communicate the results of their research in ways that will be readily understandable to a diverse audience, and participate in public discussions related to stem cell research.

All ethical principles applying to research must also be ensured in stem cell research: Principles of essentiality, of voluntariness, informed consent and community agreement, of non-exploitation, of privacy and confidentiality, of precaution and risk minimization, of professional competence, of accountability and transparency, of maximization of public interest and distributive justice, of public domain and the principle of totality of responsibility and compliance.

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